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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/800,590	Applicant(s) PETERSEN ET AL.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 14-29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 24, "the analyte" lacks antecedent basis. Note the claims now recite "nucleic acid" rather than "analyte". It is suggested that "analyte" be changed to --nucleic acid-- in view of the language employed in claim 14.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 13-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029), Wilding et al.(US 5,726,026) and Henco et al.(US 5,652,141).

The reference of Anderson et al. discloses a nucleic acid purification method which includes a cell lysing region (See column 6, line 44 to column 12, line 45). With respect to the solid phase binding within the lysing region, the reference discloses the use of posts (1908) and

Art Unit: 1744

binding reagents (1912). With respect to the use of ultrasonic means in the lysing region, the reference discloses the use of ultrasonic agitation (See column 7, line 20 and Fig. 28).

With respect to claim 13, while the reference of Anderson et al. discloses a step of forcing a sample to flow through the lysing chamber, the reference is silent as the use of a waste chamber and/or step of forcing the sample through the lysing chamber to the waste chamber.

The reference of Nelson et al. discloses that it is known in the art to enrich or preconcentrate a fluid sample within a chamber that selectively retains an analyte of interest. The reference discloses that the enrichment channel places the analyte of interest in a smaller volume than the initial sample volume (See column 3, line 56, to column 4, line 12). The reference of Nelson et al. also discloses the use of a waste chamber (63) and a step of forcing the captured material to flow into a third chamber or zone (See Figure 4).

The reference of Wilding et al. discloses (See Figures 1 and 5), that an enrichment channel such as that disclosed by the reference of Nelson et al. can be used on a sample including cells.

In view of these teachings, it would have been obvious to one of ordinary skill in the art that the time the invention was made to enrich the cells of the primary reference using an enriching chamber construction disclosed by the reference of Wilding et al. for the known and expected result of improving detection efficiency by concentrating the sample and removing potentially interfering sample substances. This would result in the use of a volume of sample that is greater than the volume of the lysis chamber. Note, the specific volume of sample employed would have been obvious based on considerations such as the source of the sample and the concentration of analyte that is desired to be obtained from the sample source.

Art Unit: 1744

With respect to the claimed filter and beads of claim 1, the reference of Henco et al. discloses that it is known in the art to employ binding material in a lysing device that captures the cells to be lysed and binds the analyte released from the cells (See column 2, lines 13-45). The reference of Henco et al. discloses the use of porous filters to retain the bead material within the lysing region of the device (See elements 2 and 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to perform the analyte separation of the method of the modified primary reference of Anderson et al. using analyte binding material within the lysing chamber as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to purify the released analyte from the cells. Using the method suggested by Henco et al. eliminates the need for a separate purification chamber in the system. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the separation beads of the modified primary reference using porous membranes as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to immobilize binding material within a desired reaction location. As a result, the upstream porous membrane would constitute a coarse filter while the binding material or filtration material subsequent to the upstream membrane would constitute the claimed second filter.

With respect to the use of a lysing buffer, both the references of Anderson et al. and Henco et al. disclose that the use of chemical agents during the cell lysis process is well known in the art and would have been obvious for the known and expected result of providing an art

Art Unit: 1744

recognized means for facilitating the release of nucleic acid sample from a sample of collected cells.

With respect to the use of agitating particles or beads and step of agitating or sonicating, the reference of Anderson et al. discloses the use of lysing particles in the chamber (See column 7, lines 1-7). Also, the reference of Henco et al. discloses the use of mechanical agitation within the lysing zone (See column 2, lines 25-39).

With respect to the further steps of amplification and detection of the sample of nucleic acid recited in claims 15-19, the reference of Anderson et al. (See sections D, E, and F encompassed by column 8, line 61, to column 16, line 53).

With respect to the volumes recited in claims 20-22, while the reference of Anderson et al. discloses a step of forcing a sample to flow through the lysing chamber, the reference is silent as to the relative volume of the sample with respect to the volume of the lysis chamber.

The reference of Nelson et al. discloses that it is known in the art to enrich or preconcentrate a fluid sample within a chamber that selectively retains an analyte of interest. The reference discloses that the enrichment channel places the analyte of interest in a smaller volume than the initial sample volume (See column 3, line 56, to column 4, line 12).

The reference of Wilding et al. discloses (See Figures 1 and 5), that an enrichment channel such as that disclosed by the reference of Nelson et al. can be used on a sample including cells.

In view of these teachings, it would have been obvious to one of ordinary skill in the art that the time the invention was made to enrich the cells of the primary reference using an enriching chamber construction disclosed by the reference of Wilding et al. for the known and

Art Unit: 1744

expected result of improving detection efficiency by concentrating the sample and removing potentially interfering sample substances. This would result in the use of a volume of sample that is greater than the volume of the lysing chamber. Note, the specific volume of sample employed would have been obvious based on considerations such as the source of the sample and the concentration of analyte that is desired to be obtained from the sample source.

With respect to the binding affinity of claims 23-25, The reference of Henco et al. discloses that it is known in the art to employ binding material in a lysing device that captures the cells to be lysed and binds the analyte released from the cells (See column 2, lines 13-45). Whether or not the same beads that art used for binding are also use for mechanical lysing would have been an obvious matter in design choice based on considerations such as the size of the cells to be lysed and/or the size of the chamber holding the beads and cells while maintaining the efficiency of the system.

With respect to the claimed sonicating during flow and/or elution of claim 26, it would have been obvious to one of ordinary skill in the art to sonicate the lysing chamber during fluid flow and/or elution of analyte for the known and expected result of improving the contact of the fluid with the binding material within the lysing chamber.

With respect to claim 27, the analyte binding step suggested by Henco et al. also discloses the use of a washing step (See column 2, line 45, and column 3, lines 52-65).

With respect to claim 28, as discussed previously, both the references of Anderson et al. and Henco et al. suggest the use of a lysing reagent.

With respect to claim 29, the configuration suggested by the reference of Henco et al. inherently provides the coarse and fine filtering. That is, the upstream porous membrane would

Art Unit: 1744

constitute a coarse filter while the binding material or filtration material subsequent to the upstream membrane would constitute the claimed second filter.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54, 63, 65, 67, 77, 78, 81, 86, 87, 89, 92, 93, 99, 104, 105, 107, 110 and 111 of copending Application No. 10/005,685 in view of Henco et al.(US 5,652,141). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application 10/005,685 encompasses the same method of lysing cells as recited in the instant claims above.

With respect to the claims use of beads and filter membrane, the reference of Henco et al. discloses that it is known in the art to employ binding material in a lysing device that captures the cells to be lysed and binds the analyte released from the cells (See column 2, lines 13-45).

Art Unit: 1744

In view of this teachings, it would have been obvious to one of ordinary skill in the art to perform the analyte separation of the method of the modified primary reference of Anderson et al. using analyte binding material within the lysing chamber as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to purify the released analyte from the cells. Using the method suggested by Henco et al. eliminates the need for a separate purification chamber in the system.

The reference of Henco et al. discloses the use of porous filters to retains the bead material within the lysing region of the device (See elements 2 and 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the separation beads of the modified primary reference using porous membranes as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to immobilize binding material within a desired reaction location. As a result, the upstream porous membrane would constitute a coarse filter while the binding material or filtration material subsequent to the upstream membrane would constitute the claimed second filter.

While the claims of application 10/005,685 disclose forces a volume of sample through the lysing chamber that is greater than the volume of the chamber and recites a ratio of at least 2:1. With respect to the specific volume of sample employed, it would have been obvious based on considerations such as the source of the sample and the concentration of analyte that is desired to be obtained from the sample source.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

2. Applicant's arguments filed 25 Feb. 2004 have been fully considered but they are not persuasive.

Applicant's arguments, see page 7, section 5., filed 25 Feb. 2004, with respect to the rejection(s) of claim(s) 1-5, 7-10 and 12 under 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Anderson et al. combined with Nelson et al., Wilding et al. and Henco et al. Note, Applicants have cancelled claims 1-5, 7-10 and 12 and filed new claims 14-29 which include different limitations than those recited in originally filed claims 1-5, 7-10 and 12.

With respect to Applicants' comments concerning the combination of the references with the reference of Henco et al., Applicants believe that the combination of the reference of Henco et al. with the previous combination of Anderson et al., Nelson et al. and Wilding et al. would not be proper because it would be "physically impossible to agitate beads to lyse cells in the porous matrix of Henco et al.'s device.

In response, the Examiner disagrees because the reference of Henco et al. clearly discloses that agitation of the disclosed matrix is possible. See column 2, lines 24-45, of the reference of Henco et al. which clearly states that lysis can include mechanical agitation of the matrix of beads.

Applicants' comments concerning the rejections of the claims with commonly owned references (See pages 8-11, sections 7-12, of the response filed 25 Feb. 2004) are persuasive and the rejections have been withdrawn.

With respect to the obviousness-type double patenting rejections of record, Applicants have submitted a terminal disclaimer, however, the terminal disclaimer has not been approved for the following reasons:

The terminal disclaimer filed on 25 Feb. 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application 10/005,685 has been reviewed and is NOT accepted.

- a. The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324.
3. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after


Art Unit: 1744

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB